



RECEIVED

JUN 20 2001

TECH CENTER 1600/2900

18. The infant formula of Claim 14 comprising DHA in an amount of about 4 mg/100 kcal to about 50 mg/100 kcal and ARA in an amount of about 4 mg/100 kcal to about 100 mg/100 kcal.

19. The infant formula of Claim 14 comprising DHA in an amount of about 5 mg/100 kcal to about 33 mg/100 kcal and ARA in an amount of about 10 mg/100 kcal to about 67 mg/100 kcal.

20. The infant formula of Claim 14 comprising DHA in an amount of about 15 mg/100 kcal to about 20 mg/100 kcal and ARA in an amount of about 30 mg/100 kcal to about 40 mg/100 kcal.

REMARKS

Claims 1-13 are pending in the present Application. Claim 4 has been objected to as informal; Claims 9-13 have been objected to as not further limiting the claims; Claims 9-13 have been rejected under the provisions of 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention; Claims 1-13 have been rejected under the provisions of 35 U.S.C. §103(a) as unpatentable over Kyle (U.S. Patent 5,374,657) in view of Crozier G.L. et al. (Monatschrift Fur Kinderheilkunde, Vol. 143, No.7, 1995, page 95-98).

The objection to Claim 4 has been obviated by amending the Claim to correct the typographical error; the objection to and rejection of Claims 9-13 has been obviated by canceling the Claims; and the rejection under 35 U.S.C. §103(a) has been overcome by pointing out the patentable distinction between the cited prior art and the present claims, as amended. New Claims 14 through 20 have been added to further define Applicant's invention. Reexamination and reconsideration of the Application, as amended, are respectfully requested.

I. The Objections to the Claims

Claim 4 has been objected to because "1.1" should be "1:1." The appropriate correction has been made by amending Claim 4. Claims 9-13 have been objected to because the effect of a method is not seen to further limit claims drawn to a method. Claims 9-13 have been cancelled to obviate the objection.

II. The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 9-13 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention because the phrase "corrected age" is not defined in the specification or in the claims. The Examiner states that the "claims are indefinite as to the "corrected age" encompassed thereby." The term "corrected age" is well known to skilled artisans as meaning the age a premature infant would be if a pregnancy had actually gone to term. For example, a premature infant born at 7 months, 2 months before the normal term of 9 months, would have a corrected age that is 2 months younger than the actual age of the infant, i.e., when the preterm infant was actually 6 months old, the corrected age would be 4 months. The formula is Corrected age equals actual age minus months premature. This permits comparison between the status of the preterm infant and normal term infants based upon age. An example of the way the term is used can be found at the website <http://staff.washington.edu/growing/Assess/Grca.htm>. The site gives a review of the use of corrected age, including definitions and examples. A copy is attached hereto as Exhibit 1.

III. The 35 U.S.C. §103(a) Rejection

The Examiner rejected Claims 1-13 as obvious over Kyle (U.S. Patent 5,374,657) in view of Crozier G.L. et al. (Monatschrift Fur Kinderheilkunde, Vol. 143, No.7, 1995, page 95-98). This rejection is respectfully traversed.

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) set forth the test for determining obviousness under 35 U.S.C. §103(a). Determining obviousness requires four kinds of factual inquiries:

- (1) the scope and content of the prior art;
- (2) the differences between the prior art and the claimed invention;
- (3) the level of ordinary skill in the field of the invention; and
- (4) any objective indicia of success such as commercial success, long felt need, and copying.

See also, Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 881, 45 U.S.P.Q.2d 1977 (Fed. Cir. 1998).

In addition, when obviousness is based upon a combination of prior art references, there must be a showing of a suggestion or motivation to combine the teachings of those references. *See Gambro Lundia AB v. Baxter Corp.*, 110 F.3d 1573, 1579, 42 U.S.P.Q.2d 1378 (Fed. Cir.

1997) (The absence of such a suggestion to combine prior art references is dispositive in an obviousness determination). *See also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582-83, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988).

Further, such a combination cannot be based upon “hindsight” that results from the use of applicant’s own invention to justify the combination. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher”). Case law makes it clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998) (a teaching or suggestion or motivation to combine references is as an essential evidentiary component of an obviousness holding). In *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 872, 228 U.S.P.Q. 90, 98 (Fed. Cir. 1985), the Federal Circuit elaborated on *Graham*:

In patent cases, the need for express *Graham* findings takes on an especially significant role because of an occasional tendency of district courts to depart from the *Graham* test, and from the statutory standard of obviousness that it helps determine, to the tempting but forbidden zone of hindsight.

III.A. The Scope and Content of the Prior Art and the Differences Between the Prior Art and the Claimed Invention

As stated by the Examiner, Kyle discloses the use of DHA and ARA in infant formula in amounts to simulate breast milk but does not address the specific and special needs of premature infants, including the difference in their ability to synthesize fatty acids and other essential nutrients needed for proper growth and development during the last part of the normal gestation term. The present invention is an improved formula specifically for preterm infants and a method for enhancing growth of preterm infants using such formula. The formula is directed to the special needs of underdeveloped preterm infants.

Crozier merely speculates that DHA and AA may be necessary for proper growth and development of premature infants based upon their necessity in fullterm infants and presence in breast milk. In essence, Crozier specifically defines the problem solved by the present invention in the discussion about the results of experiments conducted with premature infants that were fed formula supplemented with fish oil containing DHA. Crozier states that DHA was shown in the experiments to be present in the premature infant and to increase visual acuity. However, and critically, Crozier states that the growth for such premature infants was significantly depressed (Crozier, Summary, Column 2, lines 9-10). The cause of this depression in growth is unknown, although Crozier speculates a cause based upon the presence of EPA in the formulation. Basically, Crozier speculates that DHA and ARA are needed for proper growth and development but teaches that DHA significantly depresses growth. Thus, taking Crozier's teachings, one would expect the feeding of DHA to suppress, not enhance, the growth of premature infants. The present application claims the use of DHA and ARA in combination to enhance the growth of preterm infants.

When viewed carefully, Crozier in essence teaches away from the concept of enhancing growth using any formulation containing DHA. Crozier teaches that feeding DHA to a premature infant will significantly depress growth.

Critical to the understanding of Applicant's invention is the definition of "proper growth and development." Neither Kyle or Crozier disclose that administering DHA or ARA enhance the growth of premature infants. They disclose that the presence of these compounds is necessary for the "proper" growth and development of premature infants but do not teach that they can be used to "enhance" the growth of such infants. In this context, proper growth is normal growth and not enhanced growth. The present invention, in contrast, is based upon the discovery that the combination of the compounds enhance growth in premature infants, essentially enabling the premature infant to grow at an enhanced rate and catch up to expected growth norms for fullterm infants.

III.B. The Obviousness Determination

It is well established that there must be some teaching in the references which would provide a motivation or logical reason to a person of ordinary skill in the art to combine the

teachings of the references. Basically, the question in the present case is whether a fair reading of two separate and demonstratively different references as a whole would suggest such a combination to one of ordinary skill in the art at the time of the invention. There is simply no teaching in any of the references that would motivate anyone to combine patents teaching that (1) DHA and ARA are necessary for the proper (not enhanced) growth and development of fullterm infants, and (2) DHA causes a significant depression (not enhancement) in growth when fed to premature infants to achieve the present invention. The present invention uses the claimed composition to enhance the growth of premature infants and overcome the problem of depressed growth caused by DHA. There is nothing to motivate a skilled artisan to use known growth depressors in a preterm infant formula that will enhance growth.

The Examiner stated that:

A person of ordinary skill in the art would have been motivated to employ the infant formula of Kyle to preterm infants because preterm infants are known to be in need of food with sufficient amount of ARA and DHA. Once such food is administered to preterm infants, enhanced growth would be reasonably expected.

To the contrary, the references contain nothing that would motivate one to combine them to achieve the present invention. The references teach that DHA is a growth depressor not an enhancer. It is difficult to understand how enhanced growth would be reasonably expected when Crozier specifically states that DHA significantly depresses growth. If anything, Crozier teaches away from the present invention and motivates away from the use of DHA in preterm infant formulas. It is difficult to understand what would motivate a skilled artisan to place DHA in an infant formula being specifically designed to enhance growth when the art teaches that DHA significantly depresses growth. Therefore, the only possible conclusion is that the cited references provide no teaching that would motivate one to combine the references to achieve the present invention. At best, it is the impermissible use of hindsight that motivates the Examiner to combine the references now that applicant has disclosed a method for enhancing growth while including the critical ingredient DHA in an infant formula. *See In re Dance*, 160 F.3d 1338, 1343, 48 U.S.P.Q.2d 1635 (Fed. Cir. 1998) (Obviousness cannot be established by hindsight combination to produce the claimed invention).

Using the *Graham* test, it can clearly be seen that the rejected claims are not obvious in view of the cited references whether taken individually or in combination. The difference between the present invention and the prior art as disclosed in the cited references is so dramatic that the cited references could not be combined to achieve the present invention and, even if they could be combined to achieve the present invention, provide no teaching that would motivate a skilled artisan to combine the references to achieve the present invention. In fact, the cited references dramatically teach away from the present invention. The rejection under 35 U.S.C. §103(a) is therefore improper and should be withdrawn.

Applicant's new claims directed to the infant formula recite the same limitations and the present method claims. Therefore, such claims are patentable over the cited prior art for the same reasons given above.

Conclusion

In summary, the Claims have been amended and the rejections under 35 U.S.C. §112 and §103(a) have been obviated or overcome. In view of the foregoing Remarks, it is submitted that the Claims are in condition for allowance. Reconsideration of the Application, as amended, is requested and allowance of the Claims at an early date is solicited.

Mead Johnson & Company
2400 West Lloyd Expressway
Mail Stop A-21
Evansville, Indiana 47721-0001

Respectfully submitted,



Wendell Ray Guffy
Reg. No. 31,762
Phone: 812-429-7025
Facsimile: 812-429-8845



Marked-Up Copy of Amendments

4. (Amended) The method of Claim 1 wherein the ratio of ARA:DHA is 1[.]1 to 3:1.



Gaining and Growing :
Assuring Nutritional Care of Preterm Infants

EXHIBIT 1



Calculating Corrected Age

- Background
- Basics
- Calculations

Background

Assessment of growth, feeding skills, and development should be based on a corrected age for preterm infants. Use of the actual date of birth to calculate age will lead to inappropriate assessment and advice. Parents report that health professionals frequently fail to take prematurity into account. Please see section on what parents say about things that were not helpful.

Basics

- „ A full term pregnancy is estimated to be 40 weeks from the mother's last menstrual period.
- „ The Corrected age (CA) otherwise known as Gestationally Corrected Age (GCA) or sometimes just Gestational Age (GA) is based on the age the child would be if the pregnancy had actually gone to term.
- „ Chronological age (CH) is a term that is used to indicate the age from the actual day the child was born.
- „ An accurate EDC (expected date of confinement) corrected age is calculated by using that date as a birth date. For example an infant with an EDC of March 1, who was born on January 1, will have a corrected age of 3 months on June 1.

Calculating Corrected Age (CA) from Chronological Age (CH)

$$CA = CH - \# \text{ weeks or months premature}$$

Example:

- „ Baby J was born at 28 weeks gestation
- „ He was 12 weeks premature (40 weeks - 28 weeks = 12 weeks = 3 months)
- „ Today it is 6 months past the day he was actually born (6 months CH)
- „ CA = 6 months - 3 months
- „ Baby J is 3 months corrected age

Nutrition Assessment: Growth Homepage
Gaining and Growing Homepage

More information contact: Donna Johnson
Page reviewed: 4/21/2000